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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/696,289

10/29/2003

Kazumi Toyoda

10844-41US (203025)

5130

570

7590

12/14/2006

AKIN GUMP STRAUSS HAUER & FELD L.L.P.  
ONE COMMERCE SQUARE  
2005 MARKET STREET, SUITE 2200  
PHILADELPHIA, PA 19103

EXAMINER

ROZANSKI, MICHAEL T

ART UNIT

PAPER NUMBER

3768

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/696,289	<b>Applicant(s)</b> TOYODA ET AL.	
	<b>Examiner</b> Michael Rozanski	<b>Art Unit</b> 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>2-4-05, 10/29/03</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Specification***

1. The disclosure is objected to because of the following informalities: In the first sentence of paragraph [0003], the portion citing "...an fluoroscopy has been performed..." is not proper.

Appropriate correction is required.

### ***Claim Objections***

2. Claims 9, 11, and 12 are objected to because of the following informalities:

-Claim 9 recites the limitations "the plural magnetic sensors having the triaxial directivity" and "the magnetic sensors having triaxial directivity" both in the 2<sup>nd</sup> step of the claim. Claims 11 and 12 recite the limitation "the magnetic sensor" in the 4<sup>th</sup> line of each claim. There is insufficient antecedent basis for this limitation in the claims.

Appropriate action is required.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Golden et al. (US Patent No. 5,622,169). In reference to claims 1 and 9, Golden et al. disclose an apparatus and method for detecting the location of a medical tube within the body of a patient (col. 6, lines 15-17). The apparatus is capable of detecting a position and an orientation of an insertion portion of a medical insertion tool inside a body cavity. The apparatus includes a permanent magnet fixed to the end of the medical tube that serves as a magnetic field generating means (col. 6, lines 32-40). Further, the magnet requires no power source, whereby the undesirable electrical connections necessary for a power source are avoided, and maintains its magnetic field indefinitely, allowing long-term positioning and detection of medical tubes (col. 6, lines 50-57). Therefore, a magnetic field is generated without applying an electric current or conductor. The magnetic field detecting means can detect the magnetic field strength gradient produced by the magnet at distances ranging from several centimeters to several decimeters, and is disposed outside the body cavity (see Fig. 4).

Golden et al. describe a magnetic field strength sensor driver 10, including a first magnetic field strength sensor 10 and a second magnetic field strength sensor 20. However, it is also disclosed that a plurality of sensors may employed (col. 7, lines 55-56). Referring to Figure 5, the first sensor 10 includes x, y, and z-axis sensors 101, 102, and 103, respectively, while the second sensor 20 includes x, y, and z-axis sensors 201, 202, and 203, respectively (col. 12, lines 43-49). Therefore, the magnetic field detecting means includes plural magnetic sensors having triaxial directivity, wherein the sensors 10 and 20 with triaxial directivity are formed by combining plural

sensors with uniaxial directivity. Furthermore, the triaxial directivity of the plurality of sensors permits the apparatus disclosed by Golden et al. to be capable of detecting a three dimensional position and a three dimensional orientation of the insertion portion of the medical insertion tool.

In reference to claims 2 and 10, Golden et al. disclose a magnetic field strength sensor driver 10, including a first magnetic field strength sensor 10 and a second magnetic field strength sensor 20. However, it is also disclosed that a plurality of sensors may employed (col. 7, lines 55-56). Referring to Figure 3, toroidal sensors 81a, 81b are fixed near each end of an 8 cm mounting arm 82, with their detection winding axes aligned and parallel to the length of the mounting arm (col. 11, lines 29-32). The plurality of sensors having triaxial directivity are capable of being equally spaced around a scope to be detected.

In reference to claims 5, 6, 7, and 8, Golden et al. disclose a medical tube for insertion into the body. The medical tube is fully capable of being a medical insertion tool selected from among indwelling tools inside the body cavity such as a catheter, a guide wire, an endoscope or a drainage tube, a biliary stent, or a high calorie transfusion tube (col. 6, lines 15-31).

In reference to claims 3, 4, 11, and 12, Golden et al. disclose a first and second sensor 10, 20. It is noted that several different types of sensors may be used in the practice of the invention, including (but not limited to) Hall-effect, flux-gate, wound-core inductive, squid, magneto-resistive, and nuclear precession sensors (col. 7, lines 52-

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55). Therefore, the magnetic sensor of the magnetic field detecting means may be a magneto-impedance effect element.

### ***Conclusion***

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art is cited to show medical instrument location means.

US Patent No. 5,099,845 to Besz et al. disclose a catheter 40 fitted with a radiating coil 41 located in the chest cavity of a patient and a receiving coil array 44 incorporated into a hand-held unit 46.

US Patent No. 5,257,636 to White discloses an apparatus 10 for determining the optimum position of an endotracheal tube, including a magnetic sensing means 22 and an indicator 32.

European Patent No. 1,181,891 to Haynor et al. disclose a device to detect the location of a magnet coupled to an indwelling medical device, including multiple magnetic sensors to provide three dimensional measurement in the x, y, and z directions. The sensors may be spherically arranged around a patient's head (see Fig. 4).


6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Rozanski whose telephone number is 571-272-1648. The examiner can normally be reached on Monday - Friday, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MR

MR

  
ELENI MANTIS MERCADER  
SUPERVISORY PATENT EXAMINER